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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,861	09/24/2003	Donald A. Schon	MED-0005D1	9768

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,861

Applicant(s)

SCHON ET AL.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 22-35 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. With respect to the applicant's argument regarding the rejection of claims 22-25, 27-30 and 33-35, specifically that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the split distal tubes can be releasably attached or reattached) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With respect to applicant's argument that the prior art of Ash does not teach a thick internal integral septum, Examiner disagrees and refers applicant to the rejection of claim 22, where it is clearly stated that Ash teaches splittable (or frangible, i.e. releasably attached) membrane 46 which is a septum separating catheters 26 and 30 and is both integral to said catheters and internal to the catheter assembly. A clear definition of "thick" was not provided in the disclosure and the membrane of the prior art device taught by Ash is considered herein to be a thick septum.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-25, 27-30 and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Ash et al (U.S. Patent No. 5,947,953).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

- With respect to **Claim 22**: With respect to the step of forming a unitary catheter tube, Ash teaches a double catheter assembly 10 having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, first and second lumens 28 and 32 separated by a frangible membrane 46 (thick integral internal septum) to form a unitary catheter tube defined by the two separable catheters. With respect to the step of splitting the septum, Ash teaches partial splitting of septum 46 longitudinally along said distal end portion of assembly 10 to form a first distal end tube 26 and second distal end tube 30.

With respect to **Claims 23,25**: Ash teaches that the catheter assembly 10 has a generally circular cross-section and that the catheters 26,30 have a semi-circular cross section wherein respective flat surfaces 38,44 are facing one another therefore the cross section of assembly 10 would be oval. (Fig. 4F) (Col. 6, lines 1-8, Col. 7, lines 31-35)

With respect to **Claim 24**: Ash teaches that the cross sections of lumens 28,32 are circular. (Col. 7, lines 31-37)

With respect to **Claim 26**: Ash teaches that the cannulating portion 20 is formed in a single extrusion process yielding catheters with a semicircular cross section. The single extrusion process includes a step of finishing an exterior of the first and second distal end tubes by virtue of the nature of the process itself, i.e. the molten plastic forming material is drawn through a die which forms the exterior, and positive pressure is applied thereto to form the hollow space of the catheter (the lumen) as an additional step after applying the molten material to the die, thereby casting the molten material into the catheter shape with its semicircular cross section and finished exterior.

With respect to **Claims 27,28**: Please see the rejections of claims 22 and 23 as these rejections collectively address the limitations of claims 27 and 28.

With respect to **Claims 29,30**: Ash teaches separating catheters 26 and 30 along a portion of membrane 46 wherein the length of the split region is greater than the unitary region. (Fig. 1) (Col. 6, lines 42-45)

With respect to **Claim 33,34**: Ash teaches that the cannulating portion 20 of catheter assembly 10 is formed from an extrusion process. (Col. 12, lines 38-41)

With respect to **Claim 35**: With respect to the step of forming a unitary catheter tube, Ash teaches a double catheter assembly 10 having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, first and second lumens 28 and 32 separated by a frangible membrane 46 (thick integral internal septum) to form a unitary catheter tube defined by the two separable catheters. With respect to the step of

splitting the septum, Ash teaches partial splitting of septum 46 longitudinally along said distal end portion of assembly 10 to form a first distal end tube 26 and second distal end tube 30. Ash teaches separating catheters 26 and 30 along a portion of membrane 46 wherein the length of the split region is greater than the unitary region. (Fig. 1) (Col. 6, lines 42-45)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash ('953) in view of Melsky et al (U.S. Patent No. 5,704,915).

With respect to **Claims 31,32**: Ash does not teach grinding or polishing the cannulating portion 20 of catheter assembly 10. Melsky teaches a hemodialysis access device comprised of a catheter with a proximal and distal end where the distal end is split into two conduits. Melsky teaches pumping a slurry of abrasive material through shells 22 and polishing the subsequently smoothed surfaces of conical shells 22 and outlet tubes 32. Melsky teaches that it is desirable to have blood contacting surfaces be as smooth as possible to avoid thrombus formation and blood cell damage. ('915, Col. 5, lines 13-22) Since the assembly taught by Ash is also used for hemodialysis (Col. 5, lines 42-44), it would be obvious to one of ordinary skill in the art to grind and polish the outside surfaces of the catheter assembly taught by Ash.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATIANA KAEVA
SUPERVISOR & SENIOR EXAMINER

